National Health and Nutrition Examination Survey 2003-2004

Documentation, Codebook, and Frequencies

MEC Laboratory Component:

Hepatitis B surface antigen and hepatitis C antibody (confirmed).

Survey Years:
2003 to 2004

SAS Export File:
L02_C.XPT

April 2006

NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 2 - Antibody to Hepatitis B Core Antigen, Antibody to Hepatitis B Surface Antigen, Hepatitis B Surface Antigen, and Antibody to Hepatitis C Virus (Confirmed)

Years of Coverage: 2003–2004 **First Published:** April 2006 **Last Revised:** N/A

Component Description

Hepatitis viruses constitute a major public health problem because of the morbidity and mortality associated with the acute and chronic consequences of these infections. New immunization strategies have been developed to eliminate the spread of hepatitis B virus (HBV) and hepatitis A virus (HAV) in the United States. Recommendations have also been developed for the prevention and control of hepatitis C virus (HCV) infection. Because of the high rate of asymptomatic infection with these viruses, information about the prevalence of these diseases is needed to monitor prevention efforts. By testing a nationally representative sample of the U.S. population, NHANES will provide the most reliable estimates of age-specific prevalence needed to evaluate the effectiveness of the strategies to prevent these infections. In addition, NHANES provides the means to better define the epidemiology of other hepatitis viruses, including hepatitis D and E. NHANES testing for markers of infection with hepatitis viruses will be used to determine secular trends in infection rates across most age and racial/ethnic groups, and will provide a national picture of the epidemiologic determinants of these infections

Eligible Sample

Antibody to Hepatitis B Core Antigen (anti-HBc), Antibody to Hepatitis B Surface Antigen (anti-HBs), Hepatitis B Surface Antigen (HBsAg) on Anti-HBc-Positive Samples, Antibody to Hepatitis C Virus (anti-HCV confirmed): participants aged 6 years and older are eligible to be tested.

Antibody to Hepatitis B Surface Antigen (anti-HBs) only: participants aged 2–5 years are tested.

Description of Laboratory Methodology

Hepatitis B Virus Core Antibody

The Ortho HBc ELISA Test System is a qualitative enzyme-linked immunosorbent assay (ELISA) for the detection of total antibody to anti-HBc in human serum or plasma. Anti-HBc appears in virtually all individuals infected with HBV and is an accurate serological marker of

current and past infection.

ELISA procedures provide a means for routinely detecting antibodies to specific antigens. This FDA-licensed method is commercially obtained in kit form. The literature and instructions with each kit constitute the standard operating procedure (SOP) for the method.

Hepatitis B Surface Antibody

The Abbott Diagnostics AUSAB Quantitation Panel (AUSAB) for anti-HBs uses the “sandwich principle” in a solid-phase enzyme-linked immunoassay (EIA) technique to detect antibody to HBsAg in serum or plasma. Anti-HBs appear after exposure to HBsAg and is a marker for immunity following infection or as a result of vaccination.

In the AUSAB EIA, the patient specimen is incubated with polystyrene beads coated with human HBsAg. If present, anti-HBs bind to the solid-phase antigen. After washing to remove unbound material, biotin-tagged HBsAg (B-HBsAg) and rabbit anti-biotin, conjugated with horseradish peroxidase (HRPO), are incubated with the beads to form antigen-antibody-antigen “sandwich” complexes. The presence of these complexes is indicated by a colorimetric reaction produced by the addition o-phenylenediamine (OPD), a substrate for HRPO. A yellow color develops in proportion to the amount of anti-HBs in the sample and is assessed by measuring absorbance at 492 nm with a spectrophotometer. The concentration of anti-HBs in the sample is assessed by comparison to absorbances of a panel of quantitative standards run in parallel with the AUSAB EIA test kit. Levels are expressed in milli-international units per mL (mum).

Hepatitis B Surface Antigen

The AUSZYME Monoclonal test is used to detect the presence of HBsAg, which indicates current infection with HBV. Sensitive enzyme immunoassays used to detect the presence of HBsAg were first described by Engvall and Perlmann, and VanWeemen and Schuurs in 1971. In 1976 and 1977, solid-phase “sandwich” enzyme immunoassays for the detection of HBsAg were described by Wisdom, Wolters et al., and Wei et al.

Specimens that test nonreactive by the AUSZYME Monoclonal tests (Abbott Diagnostics) are considered negative for HBsAg and are not tested further. All specimens considered reactive initially are repeat-tested in duplicate using the same procedure as that used in the initial

test. If neither of the repeat tests is reactive, the specimen is considered negative for HBsAg. If the specimen is reactive in either of the repeat tests, the sample is considered repeatedly reactive.

Hepatitis C Antibody

Qualitative determination of the human antibody directed against hepatitis C virus (anti-HCV) in human serum or plasma is measured using direct solid-phase enzyme immunoassay with the anti-HCV screening ELISA. Results are expressed as "positive" or "negative" or indeterminate for anti-HCV. Positive specimens are repeated in duplicate according to the same procedure. Repeatedly positive specimens are tested supplementally using the Chiron RIBA Processor System (Chiron Corporation, Inc.). Samples where the RIBA result was positive are reported as confirmed positive for antibody to HCV
Samples where the RIBA result was negative are reported as negative for antibody to HCV and indeterminate results are reported as indeterminate.

The Chiron RIBA HCV 3.0 Strip (confirmation test)

The Chiron RIBA 3.0 Strip Immunoblot Assay (SIA; Chiron Corporation, Inc.) is an in vitro qualitative enzyme immunoassay for the detection of antibody to hepatitis C virus (anti-HCV) in human serum or plasma.

Detection of anti-HCV by SIA methodology is based upon traditional Western and dot blotting techniques, in which specific immunogens (i.e. antigenic polyproteins) encoded by the HCV genome are immobilized onto a membrane support. Visualization of anti-HCV reactivity in specimens to the individual HCV-encoded proteins is accomplished with anti-human IgG enzyme-conjugates in conjunction with a colorimetric enzyme substrate. Qualitative determination of the human antibody directed against hepatitis C virus (anti-HCV) in human serum or plasma is measured with a direct solid-phase enzyme immunoassay.
A detailed description of the laboratory method used can be found on the NHANES website.

Laboratory Quality Control and Monitoring

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed quality control and quality assurance instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols. A detailed description of the quality assurance and quality control procedures can be found on the NHANES website.

Data Processing and Editing

Blood specimens are processed, stored, and shipped to the Division of Viral Hepatitis, National Center for Infectious Diseases, National Centers for Disease Control and Prevention. Detailed specimen collection and processing instructions are discussed in the NHANES LPM. Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Analytic Notes for Data Users section below. Detailed instructions on specimen collection and processing can be found on the NHANES website.

Analytic Notes

The analysis of NHANES laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain all survey design variables and sample weights for these age groups. The phlebotomy file includes auxiliary information such as the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.

The age ranges and constraints for hepatitis testing are as follows:

- **Hep B**-The hepatitis B core antibody test is performed on all examinees 6 years old and older while the hepatitis B surface antibody test is performed on all examinees 2 years old and older. The surface antigen is tested only when the core antibody test is positive. The denominator for surface antigen has been derived to include all anti-HBc negative samples and the anti-HBc positive samples that were subsequently found to be HBsAg negative.

Note: Hepatitis B surface antigen will be released April 2006. Hepatitis B core antibody and surface antibody will be in a later release.

- **Hep C**-The screening hepatitis C antibody test is performed on all examinees 6 years old and older. Samples testing positive for anti-HCV by the screening EIA test were tested in the confirmatory RIBA assay for antibody to hepatitis C virus. Samples where the RIBA result was positive are reported as confirmed positive for antibody to HCV. Samples where the RIBA result was negative or indeterminate are reported as negative for antibody to HCV. Samples that tested negative by the screening EIA test were not tested by RIBA. These samples were reported as negative for antibody to HCV. If the antibody to Hepatitis C virus was negative, weakly positive, weakly negative or indeterminate then the confirmatory assay to the antibody to Hepatitis C virus was reported as negative and included with the negatives from the screening assay.

References

N/A

Locator Fields

Title: Hepatitis B Virus Core Antibody, Hepatitis B Surface Antibody, Hepatitis B Surface Antigen, and Hepatitis C Antibody (Confirmed)

Contact Number: 1-866-441-NCHS

Years of Content: 2003–2004

First Published: April 2006

Revised: N/A

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: Hepatitis B and C

Record Source: NHANES 2003–2004

Survey Methodology: NHANES 2003–2004 is a stratified multistage probability sample of the civilian non-institutionalized population of the U.S.

Medium: NHANES Web site; SAS transport files

National Health and Nutrition Examination Survey
Codebook for Data Production (2003-2004)

Hepatitis B surface antigen, and hepatitis C antibody (confirmed) (L02_C)

Person Level Data

April 2006

SEQN	Target
	B(6 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Respondent sequence number
English Text: Respondent sequence number.	
English Instructions:	

LBDHBG	Target
	B(6 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Hepatitis B surface antigen
English Text:	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	28	28	
2	Negative	7357	7385	
.	Missing	597	7982	

LBDHCV	Target
	B(6 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Hepatitis C antibody (confirmed)
English Text: Hepatitis C antibody (confirmed)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	87	87	
2	Negative	7269	7356	
5	Indeterminate	30	7386	
.	Missing	596	7982	